REMARKS

The Examiner rejected claims 59, 60, 65, 66, 71, 72, 77, 78, 83-85, 90, 91, 96, 97, 102, 103, 108-110, 115, 116, 121, 122, 127, 128, 133, 134, 139, 140, 145 and 146 under 35 U. S. C. § 112, first paragraph. The Examiner takes the position that the specification is not enabling for the determination of the concentration of any other component than glucose in any other biological fluid than blood in the presence of any other interferent than hematocrit.

The law on how broadly an Applicant may claim his invention is fairly well settled:

> "There is no doubt that a patentee's invention may be broader than the particular embodiment shown in his specification. A patentee is not only entitled to narrow claims particularly directed to the preferred embodiment, but also to broad claims which define the invention without a reference to specific instrumentalities."

In re Anderson, 176 U. S. P. Q. 331, 334, 471 F.2d 1237, 1241 (C. C. P. A. 1973), citing Smith v. Snow, 294 U. S. 1 (1935) and American Anode, Inc. v. Lee-Tex Rubber Products Corp., 136 F.2d 581, 585 (7th Cir. 1943).

In Anderson, the claimed invention was

> "[a] laminated dressing for a wound comprising a laminated structure made up of two layers arranged face to face, both layers being plasma-soluble, one layer constituting a primary layer adapted to be applied directly to the wound, and being more readily soluble in plasma than the other layer, the other layer constituting a secondary layer serving as a backing for said primary layer,"

and the rejection was

> "failure to satisfy Section 112, paragraph 1 * * * ."

Anderson, page 332.

The Anderson Court noted that,

> "It is quite true that the major part of appellant's specification is a disclosure of a primary layer having hemostatic properties but in determining what is disclosed we cannot restrict our consideration to the major part of the disclosure. Appellant is clearly entitled to have the whole of his disclosure considered. We have already adverted to the abstract and to original claim 1, both of which make clear that appellant did not regard his invention as limited to a hemostatic primary layer. His broad disclosures do not refer to the hemostatic property at all. Additionally, the 'prophetic' paragraph referred to by the board appears to be the one which reads:

> "'Although the primary layer is described as being hemostatic, as far as certain aspects of the invention are concerned, it need not be so, as long as it is water-soluble or plasma-soluble, and can serve as a vehicle for medication, released upon dissolution in the plasma.'
>
> "As we view it, the board's reason for agreeing that claim 1 is 'broader than warranted by the disclosure' is not because the invention as disclosed is not of equal scope with claim 1 but because the claim is inclusive of a laminated dressing in which the primary layer is of non-hemostatic material *and* because there is (1) no 'exemplification' of such a material and (2) no suggestion of 'how to use' such a material in the laminate.
>
> "On the first point, the tacitly assumed need for exemplification, we do not regard § 112, first paragraph, as requiring a specific example of everything *within the scope* of a broad claim. In re Gay, 309 F.2d 769, 50 CCPA 725 (1962). There is no question raised as to the fact that there are specific examples of what appears to be the preferred embodiment and best mode contemplated by the applicant of carrying out his claimed invention; we are here dealing only with a possible alternative embodiment within the scope of the claims. What the Patent Office is here apparently attempting is to limit all claims to the specific examples, notwithstanding the clear disclosure of a broader invention. This it may not do."

Anderson, page 333, emphasis the Court's.

Several prior art publications are incorporated by reference in the present application. The application as filed, page 1, line 15-page 3, line 15. Among the analytes mentioned in the titles of these publications are not only glucose, but also, for example, anticoagulants generally (page 2, line 11), taste compounds generally (page 2, line 26), oxygen (page 2, line 35) and lactate (page 3, line 9). Among the interferents mentioned in the titles of these publications are not only hematocrit but also, for example, suspending media generally (page 2, line 9), platelets (page 2, line 12) and urea (page 2, line 18). Additionally, the application as filed mentions at least two interferents, red blood cells and white blood cells, in the determination of glucose concentration in whole blood. The application as filed, page 4, lines 14-15. Additionally, the application states "And it is believed that the invention is useful in other systems besides glucose concentration and hematocrit. Using appropriate sensor technology, other analytes can be detected and their concentrations in a sample determined and reported." The application as filed, page 10, lines 6-8.

Thus, Anderson controls this issue, and the 35 U. S. C. § 112, first paragraph, rejection is overcome.

The Examiner rejected claims 84-104 and 133-156 under 35 U. S. C. § 112,

second paragraph. The Examiner cited certain instances of perceived indefiniteness in these claims. By certain amendments contained herein, Applicant has made a good faith effort to address the specific instances of indefiniteness noted by the Examiner. Applicant thus believes that the 35 U. S. C. § 112, second paragraph rejections of claims 84-104 and 133-156 are overcome.

The Examiner rejected claims 59-82 and 84-107 under 35 U. S. C. § 102. The Examiner relied upon Iketaki WO 99/60391 and what the Examiner identifies as its English language translation, U. S. Patent 6,576,117 (hereinafter collectively Iketaki). Iketaki teaches a statistical method for reducing the effect of an interferent, such as hematocrit, on a measurement of a biologically significant component of a body fluid, such as glucose concentration of blood. In the method taught by Iketaki, raw data concerning the concentration of the analyte, glucose in blood, for example, is obtained by providing a sample of the blood to the biosensor, applying first and second predetermined voltages (first excitation and second excitation, respectively) to the biosensor to which the sample has been provided, calculating parameters P1 and P2 from current values (If and Ib) that are obtained as a result of applying a fixed voltage (first excitation and second excitation, respectively) to the biosensor (where If is the value of maximum current or a current occurring after the maximum in the first excitation caused by applying the first predetermined voltage, and Ib is the value of current read at any point in the second excitation caused by applying the second predetermined voltage), and by correcting the errors from parameters P1 and P2 using the statistical technique. In the statistical technique, P1 is the ratio (If/Ib), and P2 is the current (Ib) read at any point in the second excitation caused by applying the second predetermined voltage. The analyte concentration is then determined using the parameters P1 and P2.

Iketaki teaches that the current value Ib is a terminal value (Ib(β)) in the second excitation current.

Iketaki further teaches at least one of two additional parameters P3 and P4 is used together with the parameters P1 and P2. P3 is a value ($I/\Delta I(\delta)$) obtained by normalizing a derivative value or a differential value at any point in the second excitation with a current value at the same point. P4 is a ratio ($Ib(\alpha)/Ib(\beta)$) of an initial current value ($Ib(\alpha)$) to a terminal current value ($Ib(\beta)$) in the second excitation. According to Iketaki, at least one of the parameters P3 and P4 is substituted with a closest expectation value when the parameter is out of an expectation range.

Iketaki teaches that a correction is performed in accordance with environmental temperature or sample temperature by preparing a plurality of correction

formulas using a statistical technique corresponding to the environmental temperature or the sample temperature and by selecting an optimum correction formula from the plurality of correction formulas. According to Iketaki, when the environmental temperature or the sample temperature corresponds to a boundary region of the temperature range used for a correction formula, both correction formulas adjacent the boundary are used, correction ranges from both correction formulas are calculated, average values or weighted average values calculated from both correction formulas are added to the current value for correction of the indicated concentration, and a corrected concentration is obtained based upon an additional value.

Iketaki teaches that a discriminant function is selected from the parameters P1 and P2. A discriminant score is obtained from the discriminant function and the concentration of the analyte is calculated from a correction range proportional to the discriminant score. A range to calculate the concentration of the analyte depending on a fixed correction range regardless of the discriminant score, and a range to calculate the concentration of the analyte without performing a correction, are set.

Iketaki also teaches a measurement apparatus comprising a meter for measuring an environmental temperature or a sample temperature, a detector for detecting sample feeding, a device for applying a certain voltage to a biosensor at a predetermined point of time, a meter for measuring a value of current generated by an electrochemical reaction, and a converter for converting the measured value of the current into a concentration of the analyte in the sample. The apparatus includes means for measuring the concentration of an analyte, means for feeding a sample, means for applying first and second predetermined voltages to the biosensor after sample feeding, means for calculating parameters P1 and P2 from current values that are obtained as a result of applying a fixed voltage to the biosensor, and means for correcting errors of a measured value using these parameters by a statistical technique. P1 is a ratio (If/Ib), where (If) is the value of maximum current or a current occurring after the maximum in a first excitation caused by applying the first predetermined voltage, and (Ib) is the value of current read at any point in a second excitation caused by applying a second predetermined voltage after the first predetermined voltage. P2 is a current (Ib) read at any point in the second excitation caused by applying the second predetermined voltage.

Iketaki's approach to correction of an indicated concentration for the concentration(s) of (an) interferent(s) is thus statistical, and not based upon measurement(s) of the concentration(s) of the interferent(s), as distinguished from Applicant's approach,

reflected in Applicant's claims, wherein correction of the indicated concentration of the analyte is based upon measurement(s) indicating the concentration(s) of the interferent(s) in question. This distinction is reflected, for example, in the following recitations from Applicant's claim 59:

> "[P]erforming a first measurement on the biological fluid or control which first measurement varies with both the concentration of the first component and at least one of the presence and concentration of the second component, performing a second measurement on the biological fluid or control which second measurement has the form of a time-varying function $i_2(t)$, where t is time, t < some arbitrarily established time, $i_2(t)$ varying primarily only with the at least one of the presence and concentration of the second component to develop an indication of the at least one of the presence and concentration of the second component * * * ."

This distinction is also reflected, for example, in the following recitations from Applicant's claim 84:

> "[A] device for performing a first measurement on the biological fluid or control which first measurement varies with both the concentration of the first component and at least one of the presence and concentration of the second component, the device further being for performing a second measurement of a time-varying function $i_2(t)$ of the biological fluid or control, where t is time, t < some arbitrarily established time, which second measurement varies primarily only with the at least one of the presence and concentration of the second component to develop an indication of the at least one of the presence and concentration of the second component * * * ."

Iketaki neither discloses nor suggests such methods as the methods disclosed and claimed in the present application. The 35 U. S. C. § 102 rejections of claims 59-82 and 84-107 based upon Iketaki are thus overcome.

All of claims 59-156, as amended herein, are thus believed to be in condition for allowance. Such action is respectfully requested.

The Commissioner is hereby authorized to any fees which may be required to constitute this a timely response to the September 21, 2004 official action, to Applicant's undersigned counsel's deposit account 10-0435 with reference to file 5727-65832. A duplicate copy of this authorization is enclosed for that purpose.

Respectfully submitted,

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